K112999

NOV 22 2011

# Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Submitter's Name:**

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**Contact Information:**

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**Date of Preparation:** November 15, 2011

**Name of Product:**

Dimension® RxL/RxL Max clinical chemistry analyzer (with Linux Operating System)

**FDA Classification Name:**

Discrete photometric chemistry analyzer for clinical use (Class I)

**Predicate Device:**

The following table describes the predicate device, device classification, regulation and product code associated with this pre-market notification:

| New Product | Predicate Device | Predicate 510(k) | Device Class | Regulation | Product Code |
|---|---|---|---|---|---|
| Dimension® RxL/RxL Max clinical chemistry analyzer (with Linux Operating System) | Dimension® RxL/RxL Max clinical chemistry analyzer (with QNX Operating System) | K963498 | I | 862.2160 | JJE |

**Device Description:**

The Siemens Healthcare Diagnostics Dimension® clinical chemistry analyzers are floor model, fully automated, microprocessor-controlled, integrated instrument systems that use prepackaged Flex® reagent test cartridges to measure a variety of analytes in human body fluids. The systems can process samples in random access, batch and stat modes. The systems are multi-functional analytical tools that process chemical and immunochemical methodologies, utilizing photometric, turbidimetric, and integrated ion selective multisensor detection technologies for clinical use. The Dimension systems include the ability to communicate and connect with laboratory information system (LIS) networks.

With revision 10.0 software, the Operating System of the Dimension clinical chemistry analyzers, RxL/ RxLMax (K963498), Xpand /Xpand Plus (K010061), will change from QNX to Linux.

**Intended Use:**

The Dimension ® clinical chemistry system is an *in vitro* diagnostic device intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, mixing, heating, and measuring spectral intensities to determine a variety of analytes in human body fluids.

The Dimension system chemical and immunochemical applications utilize photometric, turbidimetric, and integrated ion selective multisensor technology for clinical use.

## Comparison to Predicate Device:

The Dimension® clinical chemistry systems with the Linux operating system (revision 10.0 software) and the predicate Dimension systems employ prepackaged reagents in flexible plastic, Siemens Flex® reagent cartridges. Both systems automatically process and analyze clinical samples using a variety of *in vitro* diagnostic test methods. Both systems utilize integrated, ion selective multisensor detection technology for analysis of sodium, potassium and chloride electrolytes. A comparison of the important similarities and differences is provided in the following table:

| Similar Features | Test Devices (with Linux) | Predicate Devices (with QNX) |
|---|---|---|
| Intended Use | *in vitro* diagnostic use | *in vitro* diagnostic use |
| System Control | Fully automatic, microprocessor controlled | Fully automatic, microprocessor controlled |
| User Interface | Keyboard control<br>Stationary barcode scanners<br>Graphical user interface | Keyboard control<br>Stationary barcode scanners<br>Graphical user interface |
| Detection Technologies | photometric<br>turbidimetric<br>multisensor electrodes, ion selective | photometric<br>turbidimetric<br>multisensor electrodes, ion selective |
| Reagents | Prepackaged, 6 & 8 well plastic, Siemens Flex® reagent cartridges stored on board | Prepackaged, 6 & 8 well plastic, Siemens Flex® reagent cartridges stored on board |
| System fluids and Supplies | Stored on board | Stored on board |
| Reaction Vessels | soft, plastic cuvettes & plastic reaction vessels | soft, plastic cuvettes & plastic reaction vessels |
| Temperature control | Reactions are controlled at 37°C<br>Reagents are stored at 2 to 8 °C | Reactions are controlled at 37°C<br>Reagents are stored at 2 to 8 °C |
| Spectral Selection | Interference filters - quartz/halogen lamp source | Interference filters - quartz/halogen lamp source |
| Test Throughput (typical) | Up to 500 tests/hr | Up to 500 tests/hr |

| | | |
|---|---|---|
| LIS external connectivity capability | Yes | Yes |
| System Performance Monitoring | Traditional preventative maintenance (time-based) | Traditional preventative maintenance (time-based) |
| Sample Level Detection Capability | Automatic | Automatic |
| Calibration/QC | Manual calibration/QC | Manual calibration/QC |
| Sample Integrity (hemolysis, icterus, lipemia) Monitoring | Yes - spectral interference monitoring (optional) | Yes- spectral interference monitoring (optional) |

| **Different Features** | **Test Devices** | **Predicate Devices** |
|---|---|---|
| Operating System | Linux | QNX |
| Data storage device | USB | Floppy disk |
| Designated Printed Circuit Boards | RoHS compliant | Not RoHS compliant |

**Comments on Substantial Equivalence:**
Models of the Dimension® clinical chemistry systems are designed similarly for the same purpose. They are floor model units that are microprocessor-controlled, integrated instrument systems that use prepackaged, Siemens Healthcare Diagnostics Flex® reagent cartridges and integrated ion selective multisensor technology to analyze a variety of analytes in human body fluids. The instruments spectrally analyze processed clinical samples using chemical and immunochemical methodologies. To ensure substantial equivalence with the Operating System change, representative methods were tested on instruments with QNX based software and compared to results of the same samples and methods on instruments updated with the Linux Operating System (revision 10.0 software). The representative methods, Na, K, Cl, GLUC, TSH and AST, were chosen to exercise different detection technologies on the instruments.

Comparative data for Method Comparison and Precision (with in run, within lab) demonstrate equivalent performance in evaluations of the representative methods.

**Conclusion:**
The Dimension® clinical chemistry systems with the Linux Operating System (revision 10.0 software), are substantially equivalent in principle and performance to Dimension® clinical chemistry systems with QNX operating systems, based on the similarity of system design and comparative data from representative methods.

Lorraine H Piestrak
Regulatory Affairs & Compliance Manager
November 15, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 22 2011

Siemens Healthcare Diagnostics
c/o Lorraine H. Piestrak
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Newark, DE 19714-6101

Re: K112999
Trade Name: Dimension Clinical Chemistry System
Regulation Number: 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: CFR, JJE, CEM, JGS, CGZ, CIT, CEW
Dated: October 6, 2011
Received: October 24, 2011

Dear Lorraine H. Piestrak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K112999

Device Name:

Dimension® clinical chemistry systems with Linux Operating System (revision 10.0 software) with:

- Dimension® QuikLYTE® Integrated Multisensor ($NA^+$ / $K^+$ / $Cl^-$)
- Dimension® Glucose Flex® Reagent Cartridge (GLUC)
- Dimension® Thyroid Stimulating Hormone Flex® Reagent Cartridge (TSH)
- Dimension® Aspartate Aminotransferase Flex® Reagent Cartridge (AST)

Indications For Use:

Sodium measurements are used for monitoring electrolyte imbalances.

Potassium measurements are used for diagnosis in diseases with high and low Potassium levels.

Chloride measurements are primarily use to detect and treatment of metabolic disorders.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Thyroid stimulating hormone measurements are used in diagnosis of thyroid or pituitary disorders.

Aspartate aminotransferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off



Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K112999

# Indications for Use

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